

**REMARKS**

Upon entry of the present amendment, claims 1 and 3-19 are pending in the application, of which claims 1 and 5 are independent. Claim 2 has been canceled without prejudice, and without dedication or abandonment of the subject matter therein. In light of such cancellation, the objection presented at the bottom of page 2 of the Office is believed to be overcome.

Claims 1, 4, 5, 10-12 and 15 have been amended to be more consistent with each other, and with the invention disclosure. Particularly, claims 1, 5 and 12 are amended to better reflect that the ordinary test tubes used as sample holders according to the present invention do not have precisely the same optical characteristics as each other, while claims 5 and 10-12 insert the term --interchangeable-- before "test tubes", and claim 15 further defines the plurality of test tubes consistent with amended claim 1.

Applicant respectfully submits that the above amendments are fully supported by the original disclosure, and that such amendments do not introduce any "new matter" into the application.

The above-identified Office Action has been reviewed, the references carefully considered, and the Examiner's comments carefully weighed. In view thereof, the present Amendment is submitted. It is contended that by the present Amendment, all bases of rejection set forth in the Office Action have been traversed and overcome. Accordingly, reconsideration and withdrawal of the final rejection is respectfully requested.

**The Rejections of the Claims:**

1. In the Office Action, claims 1, 2, 5-11, 13, 18 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-15,

and 19 of US Patent No 6,791, 674. Applicant is filing concurrently herewith a "Terminal Disclaimer to Obviate A Double Patenting Rejection Over A 'Prior' Patent". Therefore, this rejection is believed to be overcome, and it is respectfully requested that such rejection be reconsidered and withdrawn.

2. In the Office Action, claims 1-4 and 14-16 are rejected under 35 USC §103(a) as being unpatentable over Soller et al. (6,006,119) in view of Wright et al. (6,483,583); Claims 5, 6, 8-14 and 17 are rejected under 35 USC §103(a) as being unpatentable over Soller et al. and Wright et al. and further in view of Brown et al. (4,134,678); Claim 7 is rejected under 35 USC §103(a) as being unpatentable over Soller et al. and Wright et al. in view of Brown et al. and Alfano et al. (US 6,006,001); and Claims 18 and 19 have been rejected under 35 USC §103(a) as being unpatentable over Soller et al. and Wright et al. in view of Brown et al. and Ikeda et al. (4,939,674).

#### Applicant's Response

Upon careful consideration applicant respectfully traverses the above rejections of the claims, and submits that each of claims 1 and 3-19 is clearly patentably distinct over the Soller et al., Wright et al., Brown et al., Alfano et al. and Ikeda et al. references (whether considered singly or in combination), for the reasons discussed below.

Initially, applicant respectfully submits that Soller is *fundamentally deficient* in relation to the presently claimed invention not only because he fails to use measured intensity of light transmitted through a ceramic plate as a reference value, but also because he fails to teach or suggest many other significant features of the claimed invention.

Soller is primarily concerned with non-invasive optical measurement of blood hematocrit through a subject's skin, rather than measurement of blood samples that have been withdrawn

from the subject. Although Soller teaches an apparatus (his Fig. 14) for measuring a blood sample contained in a sample holder, such apparatus uses a very specialized quartz cell for measuring liquid samples, i.e., the special quartz cuvette 1061. Thus, is fundamentally distinct from the present invention in that he fails to teach or suggest: using a plurality of interchangeable test tubes having substantially the same optical specifications as a sample test tube for determining a calibration equation (claim 1); using a plurality of test tubes having substantially the same optical specifications for containing a liquid sample to obtain a spectrum of the liquid sample, which is modified using a calibration equation (claim 5); using ordinary test tubes with substantially the same optical specifications as the plurality of interchangeable test tubes (claim 4); using ordinary test tubes as the test tubes which contain the liquid sample (claim 10); using the interchangeable test tubes for containing the reference liquid sample in determining the calibration equation (claim 11); using ordinary test tubes with substantially the same optical specifications for containing the liquid samples during spectrum measurement of the sample (claim 12); using ordinary test tubes as the sample test tube and the test tubes having substantially the same optical specifications as the sample test tube receptacles (claim 14); and wherein a liquid sample being analyzed is an unmodified field sample (claims 16, 17); etc.; and wherein the analysis is performed using near infrared light with a wavelength in a range of 700nm – 1100nm.

Soller's quartz cell transmits light very well, and thus the wavelength of light used is distinct from that used in the present invention. Since the present invention uses only ordinary (inexpensive), interchangeable test tubes, the test tubes do not have precisely matched optical characteristics, but instead have having substantially the same optical specifications. Further, ordinary test tubes do not transmit light very well, and thus a specific wavelength of 700-1100

nm must be used.

As reflected in the language of claim 1 and discussed on page 3 of the present specification, "In the spectrum measurement of the sample for making the calibration equation, it is preferable to use a plurality of tubes with the same specification." This means that, to attain the calibration curve, a plurality of test tubes which contain the same sample of liquid are measured and averaged. The results from plural test tubes have to be averaged because the result of each test tube is not so accurate. However, averaging the result of many test tubes allows a user of this apparatus – method to use any such ordinary test tube in the field during the actual testing of liquid samples. Even if one or more of the ordinary test tubes breaks during such testing, any other such ordinary test tube can be used, permitting the testing to quickly resume. This aspect of the invention, i.e., use of the plurality of interchangeable test tubes having substantially the same optical specifications for determining the calibration equations and performing field tests, is very important – advantageous as a practical matter, and is not disclosed or suggested by conventional measurement methods/apparatus including that of Soller. Note, for example, in the disclosure of Soller, *the same* "quartz cuvette 1061 is used through the entire experiment" (col. 20 lines 7-8). Still further, from the discussion at Soller's col. 19, line 45 – col. 20, line 42, it is clear that the quartz cuvette 1061 used in measuring blood samples is not the same as the receptacle used to collect 500 ml sample from a pig, ", while Soller also specifically uses capillary tubes (not the quartz cuvette) for generating his calibration equation, as discussed at his col. 20, lines 1-5 .

With respect to the proposed modification of Soller's method based on the disclosure of Wright, applicant points out that Wright relates to analysis of (solid) objects, specifically agricultural products such as grain or forage, rather than to analysis of liquid samples contained in quartz cuvettes as in Soller. Moreover, Soller already specifically provides that a reference value

for his analysis is acquired "... using the blank cuvette as a reference" (see his col. 20, lines 14-17).

As such, persons skilled in the art would not have considered it obvious at the time of the invention to hypothetically modify Soller's method in the manner proposed by the Examiner because the references provide no motivation for doing so. The analysis of solid (grain) products is not the same as the analysis of liquids such as blood, e.g., different sample collectors, different sample holders, etc., and there is no indication that the ceramic tile used to calibrate a spectrometer for solids analysis would be appropriate for the liquid analyzing spectrometer of Soller.

Regarding the Examiner's rejection of claims 5, 6, 8-14, and 17 as being unpatentable over Soller and Wright and further in view of Brown et al., and the Examiner's rejection of claim 7 as being unpatentable over Soller, Wright, Brown and further in view of Alfano et al., applicant respectfully traverses such rejection for those reasons stated above with respect to Soller and Wright which are not overcome by any additional teachings of Brown or Alfano.

Further, with regards to Examiner's rejection of claims 18 and 19 over Soller and Wright and further in view of Brown and Ikeda, applicant respectfully traverses such rejection for those reasons as stated above with respect to Soller and Wright which are not overcome by any teachings of Brown or Ikeda, and because the proposed modification of Soller's apparatus relative to a select teaching of the Ikeda reference, is improperly based on a suggestion coming entirely from the Examiner (guided by impermissible hindsight of applicant's disclosure), rather than on any teaching or suggestion which may be fairly gleaned from the teachings of the references.

Regarding the proposed modification, we note that Ikeda's apparatus is very distinct from the NIR apparatus – method of Soller (as well as that of the presently claimed invention). For

example, Ikeda's apparatus involves rotation of a sample chamber for the blood platelet or cell suspension, and wherein the gap (distance) between the rotor and the inner bottom surface of the chamber is adjusted to select an appropriate shear stress to be applied to the suspension in the chamber, as well as to achieve an optical path length not less than 1 cm. The sample cuvette in Soller's apparatus – method does not involve the discussed features of Ikeda's system.

Correspondingly, persons of ordinary skill in the art would not consider it obvious to hypothetically modify Soller's apparatus to include the discussed select feature (optical path length) of Ikeda's apparatus, because the references provide no motivation for doing so.

Based on the foregoing, the rejection of claims 1-4 and 14-16 based on the Soller and Wright references, the rejection of claims 5, 6, 8-14, and 17 based on the Soller, Wright and Brown references, the rejection of claim 7 based on the Soller, Wright, Brown and Alfano, and the rejection of claims 18 and 19 based on Soller, Wright, Brown and Ikeda are believed to be overcome in relation to present claims 1 and 3-19, and it is respectfully requested that such rejections be reconsidered and withdrawn.

#### Other Matters

The additional reference cited by the Examiner, Kobayashi et al. US Patent 6,281,499, has been considered by applicant, but it is respectfully submitted that this reference does not overcome the deficiencies of Soller et al., Wright et al., Brown et al., Alfano et al. and Ikeda et al. as discussed above in relation to the present claims.

#### Conclusion

Based on all of the foregoing, applicant respectfully submits that all of the objections and rejections set forth in the final Office Action are overcome, and that as presently amended, all of the pending claims are believed to be allowable over all of the references of record, whether

considered singly or in combination.

Applicant requests reconsideration and withdrawal of the rejections of record, and allowance of the pending claims.

Applicant respectfully submits that the above amendments are fully supported by the original disclosure, including the drawings and claims, no new matter is introduced by the above amendments. The application is now believed to be in condition for allowance, and a notice to this effect is earnestly solicited.

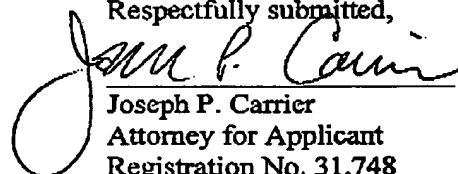
If the Examiner is not fully convinced of the allowability all of the claims now in the application, applicant respectfully requests that the Examiner telephonically contact applicant's undersigned representative to expeditiously resolve prosecution of the application.

In relation to the Terminal Disclaimer To Obviate a Double Patenting Rejection Over a "Prior" Patent, as filed herewith, the Commissioner is hereby authorized to charge the requisite fee of \$130.00 (37 CFR 1.20(d)) to Deposit Account No. 50-0744 in the name of Carrier, Blackman & Associates, P.C. A duplicate copy of this sheet is enclosed.

Favorable reconsideration is respectfully requested.

Customer No. 21828  
Carrier, Blackman & Associates, P.C.  
24101 Novi Rd, Ste. 100  
Novi, Michigan 48375  
September 7, 2005  
AMC/jpc  
Enclosures

Respectfully submitted,

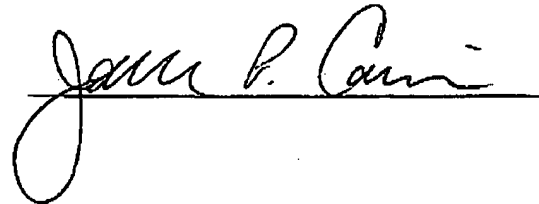
  
Joseph P. Carrier  
Attorney for Applicant  
Registration No. 31,748  
(248) 344-4422

**CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is being submitted via facsimile transmission to the US Patent & Trademark Office, on September 7, 2005.

Dated: September 7, 2005

13



considered singly or in combination.

Applicant requests reconsideration and withdrawal of the rejections of record, and allowance of the pending claims.

Applicant respectfully submits that the above amendments are fully supported by the original disclosure, including the drawings and claims, no new matter is introduced by the above amendments. The application is now believed to be in condition for allowance, and a notice to this effect is earnestly solicited.

If the Examiner is not fully convinced of the allowability all of the claims now in the application, applicant respectfully requests that the Examiner telephonically contact applicant's undersigned representative to expeditiously resolve prosecution of the application.

In relation to the Terminal Disclaimer To Obviate a Double Patenting Rejection Over a "Prior" Patent, as filed herewith, the Commissioner is hereby authorized to charge the requisite fee of \$130.00 (37 CFR 1.20(d)) to Deposit Account No. 50-0744 in the name of Carrier, Blackman & Associates, P.C. A duplicate copy of this sheet is enclosed. *JPC*

Favorable reconsideration is respectfully requested.

Customer No. 21828  
Carrier, Blackman & Associates, P.C.  
24101 Novi Rd, Ste. 100  
Novi, Michigan 48375  
September 7, 2005  
AMC/jpc  
Enclosures

Respectfully submitted,

*Joseph P. Carrier*  
Joseph P. Carrier  
Attorney for Applicant  
Registration No. 31,748  
(248) 344-4422

**CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is being submitted via facsimile transmission to the US Patent & Trademark Office, on September 7, 2005.

Dated: September 7, 2005

Duplicate